

Cytotoxicity Failure Program

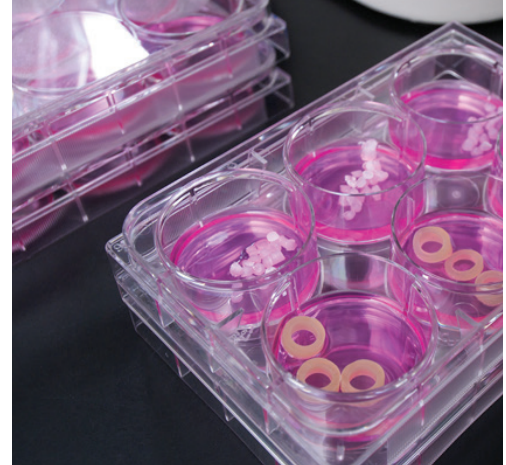
Cytotoxicity Failures

Cytotoxicity testing is designed to demonstrate if there are cytotoxic leachable substances from medical devices or materials. Cytotoxicity testing is the most sensitive biocompatibility test and is used for safety testing of all medical devices with patient contact. It is also used frequently as a routine screening test for raw materials.

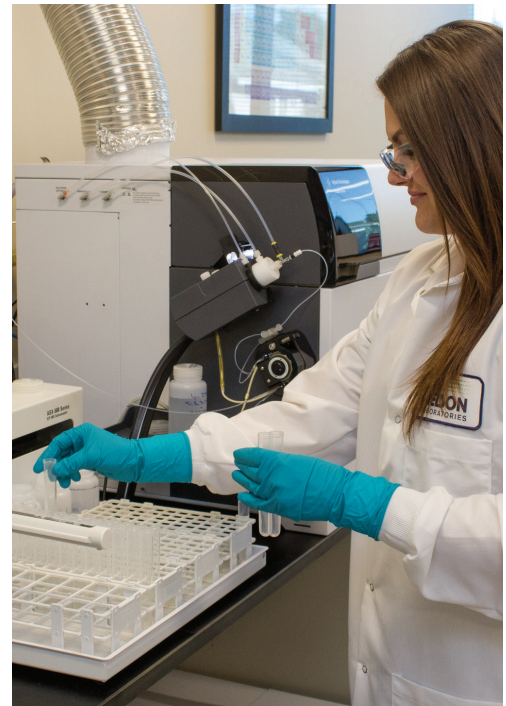
Occasionally, a device or material will exhibit a level of cytotoxic reactivity that is higher than what is allowed by the ANSI/AAMI/ISO 10993-5 standard and will result in a failed test. Although your product may have failed a cytotoxicity test, it doesn't necessarily mean that your device or material is unsafe for clinical use. It simply means that you are obligated to identify the source of the failure and assess any toxicological risks. There are several possible causes for a failure and Nelson Labs provides services to help you assess the failure and any toxicological risks.

Cytotoxicity Failure Program

In the past, if your product failed cytotoxicity testing, you would need to send new samples for additional testing to determine the cause of the failure. We have recently added a new service to help our customers potentially save time and money when conducting these evaluations. If you request the Nelson Labs Cytotoxicity Failure Program, when submitting your samples to the lab, we will store a sample of the extraction fluid from your cytotoxicity test until you receive your test results. In the case of a failing result, we will connect you with one of our subject matter experts who will help you develop a plan for investigation. Because we have retained a sample extract from your original cytotoxicity test, we can quickly test the retained fluid without the need for a new sample. We typically test for metals in these cases, as the presence of metals from the manufacturing process, handling, or colorants is a primary cause for failed cytotoxicity tests.



Cytotoxicity testing



ICP-MS metals analysis

Contact our team of experts today
to learn how we can get your product to market.

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US FDA registered and third-party accredited to ISO 17025 standards

If the test detects cytotoxic metals in the extract, we will then contact you with details regarding initiating a toxicological risk assessment. Our toxicologists can assess the metals and determine if the concentration would be sufficient to lead to any patient safety issues. This analysis can also be helpful to decide if an investigation regarding the source of the contamination should be conducted.

Customer Benefits

- Preservation of the original sample extract will allow us to quickly conduct a failure investigation to help identify and eliminate any potential causes.
- No need to provide additional samples, which could increase costs and delay testing.
- Follow-up testing will not only identify if cytotoxic metals are present in the sample, but also provide a quantitative analysis of those metals.
- If requested, the toxicological risk assessment will evaluate if the concentration of metals found would be sufficient to lead to any patient safety issues.

Your products are as important to us as the patients they represent.

That is why we deliver:

- Improved patient outcomes & minimized risk
- Resolution to complex problems
- Superior testing solutions and service
- Increased product safety and efficacy



Toxicology Consulting Team

Our goal at Nelson Laboratories is to help you achieve success. Before your next cytotoxicity test, contact your Nelson Labs sales rep or call **800-826-2088**, to determine if this program can help move your project forward.

Industries

Nelson Laboratories offers a broad range of regulatory compliance and product performance evaluations for:



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TISSUE



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CONSULTING

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